



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2010-0023]

Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: New Schedule for Implementation of Routine Testing and Verification Activities.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing a new date for when it will implement routine verification sampling and testing for raw beef manufacturing trimmings for six non-O157 Shiga toxin-producing Escherichia coli (STEC) serogroups (O26, O45, O103, O111, O121, and O145). This new date will provide additional time for establishments and laboratories to validate their test methods. FSIS announced in September 2011 plans to test certain raw beef products for these six STEC serogroups in addition to O157:H7. FSIS has determined that these organisms are adulterants of raw ground beef products and product components under the Federal Meat Inspection Act (FMIA).

DATES: Beginning June 4, 2012, FSIS will implement routine verification activities, including testing, for the six additional STEC discussed in this document (O26, O45, O103,

0111, 0121, and 0145), of raw beef manufacturing trimmings (domestic or imported) derived from cattle slaughtered on or after June 4, 2012. To facilitate compliance with the policy, and to allow industry time to implement any necessary changes in their food safety systems, FSIS will generally not regard raw, non-intact beef products or the components of these products found to have these pathogens as adulterated until June 4, 2012. FOR FURTHER INFORMATION CONTACT: Daniel Engeljohn, Ph.D., Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On September 20, 2011, FSIS published a Federal Register notice announcing a final determination that raw, non-intact beef products or raw, intact beef products that are intended for use in raw, non-intact product, that are contaminated with Shiga toxin-producing Escherichia coli (STEC) 026, 045, 0103, 0111, 0121, and 0145, are adulterated within the meaning of 21 U.S.C. 601(m)(1) and (m)(3) (76 FR 58157; Sep. 20, 2011).

FSIS announced that it intended to implement a verification sampling and testing program for the six non-0157 STEC, as it already does for E. coli 0157:H7. The Agency intended to begin this verification sampling and testing on March 5, 2012. The

Agency noted that it would initially sample raw beef manufacturing trimmings and other ground beef components for the six non-O157 STEC, but that it would consider other products, including raw ground beef, contaminated with these STEC to be adulterated (76 FR 58160). The Agency asked for comments on its plans for implementing the program (76 FR 58157, 58164).

In addition, FSIS asked for comments on: Agency plans for a baseline survey of relevant STEC prevalence in raw beef products, whether to hold technical or other public meetings, validation guidance for pathogen detection test kits, various cost estimates, the type of outreach and information that would be most useful to establishments preparing for implementation of the Agency's policy, and information that foreign governments might need to address inspection equivalency or implementation concerns.

In response to comments, FSIS extended the public comment period from November 21, 2011, to December 21, 2011, and held a public meeting by teleconference on December 1, 2011 to solicit comments (76 FR 72331; Nov. 23, 2011). FSIS intends to publish a Federal Register notice discussing and responding to the comments that it received.

Many of the comments requested a delay of the implementation date for testing for the relevant STECs for

various reasons, including the need for test kits to detect these organisms to become more widely available.

While FSIS is confident that reliable test kits will be available for commercial use before March 5, allowing additional time for beef establishments to begin sampling and testing with these new kits will facilitate compliance with the non-O157 STEC policy. Accordingly, beginning the week of June 4, 2012, rather than on March 5, FSIS will begin scheduling verification tasks for non-O157 STEC control of raw beef manufacturing trimmings. FSIS will collect excision (N60) samples for testing raw beef manufacturing trimmings derived from cattle slaughtered on or after June 4, 2012, for the seven relevant STECs (O157:H7 plus O26, O45, O103, O111, O121, and O145). For production lots of raw beef manufacturing trimmings not accompanied by documentation showing the date of slaughter of the cattle from which the beef was derived, or for production lots that contain mixtures of raw beef manufacturing trimmings derived from cattle slaughtered before and after June 4, 2012, FSIS will sample the production lot only for O157-STECS. For production lots of raw beef manufacturing trimmings not accompanied by documentation showing that the date of slaughter of the cattle from which the beef was derived, or for production lots that contain mixtures of raw beef manufacturing trimmings derived from cattle slaughtered before and after June 4, 2012, FSIS will sample the

production lot only for O157 STEC. For production lots with documentation that the beef in the production lot contains only product derived from cattle slaughtered on or after June 4, 2012, FSIS will test the samples for the seven relevant STECs. The slaughter date of June 4, 2012, is important for implementing the verification testing program for raw beef manufacturing trimmings because FSIS can be certain that, as of this date, trimmings derived from cattle slaughtered on or after this date will have been produced under a slaughter and further processing system that the Agency expects to control for the six additional STEC.

With the implementation of verification testing for beef manufacturing trimmings on June 4, FSIS will also consider raw, non-intact beef products or raw, intact products intended for use in non-intact beef products that are contaminated with STEC O26, O45, O103, O111, O121, and O145, to be adulterated within the meaning of 21 U.S.C. 601(m)(1) and (m)(3). FSIS will generally not regard raw, non-intact beef products found to have these pathogens as adulterated until it implements this verification testing program. However, if product is associated with an STEC outbreak before that time, the product will be deemed adulterated and subject to recall, consistent with current FSIS practice.

Finally, the Agency notes that in February 2012, it contacted foreign governments already approved for the export of raw beef to the United States and informed them that FSIS would make a limited amount of reagents used in the FSIS laboratory method for non-O157 STECs available to a foreign government if that government wanted to conduct a comparative analysis of its method and methods used with test kits assessed by FSIS. Although these comparative analyses are not a necessary precondition for FSIS to begin verification testing of raw beef manufacturing trimmings on June 4, 2012, FSIS believes that the results of such comparative analyses could be useful.

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Done, at Washington, D.C.: February 14, 2012

Alfred V. Almanza,

Administrator.

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